Chapter 12

LABORATORY

12.1. Laboratory Services. Appropriate laboratory services shall be available to DIHS providers in support of the clinical screening, diagnosis, treatment, and management of detained aliens. Each laboratory will obtain a Clinical Laboratory Improvement Amendments (CLIA) waiver for testing utilized for screening purposes.

12.1.1. On-Site. Minimum laboratory services available onsite shall include:

XGlucose Dextrostick/Hemocue
XUrinalysis Dipstick
XUrine Pregnancy Test
XH. Pylori Finger Stick Test
XFecal Occult Blood
XHgA1C
XUrine Microalbumin
XMicrohematocrit
XStrep A

12.1.2. Off-site. Any outside laboratory facilities used must be accredited by CAP or licensed by the CDC. Local operational procedures for these services will include the following:

XThe name, address, and telephone number of the clinical laboratory utilized
XMethods to obtain certain specimens
XHow specimens are to be stored
XHow specimens are prepared for transport
XHow routine and stat results are to be obtained
XBill review process
XInventory and ordering process for laboratory supplies

12.2. Staffing and Organization. The clinic staff assigned to the laboratory will collect and prepare specimens for outside lab work and perform on-site CLIA waived lab tests under the supervision of the HSA and clinical guidance of the CD.

12.3. Laboratory Services for Sick Call. Guidelines for ordering lab services for a detainee brought to the medical facility for sick call or medical appointment are as follows:

XOnly Medical Staff providers can order lab work.
XAll laboratory orders must be documented in the detainee's medical record.
XThe detainee will be brought to the laboratory along with the record.
XAll detainees with lab orders will have a Return-to-Clinic appointment.

XAfter a test has been performed, it will be documented in the record as follows:
- Xdate
- Xtime
- Xtest(s) performed
- Xsignature of person obtaining specimen

XAll laboratory results will be brought to the attention of the physician or designee for further evaluation as warranted. The original report will be signed by the physician or designee, dated, and forwarded to Medical Records for inclusion in the patient's medical record.

XResults will be logged in the proper laboratory log book the day the results are received.

12.4. Preparing Specimen for Transport. All specimens are to be packaged for transport, with a record kept of all specimens sent to the reference lab, in accordance with the following:

XAll red tops spun down.

XSpecimens labeled with the patient's name, alien number, date, sex, and age.

XCultures labeled as above, including site (i.e., right leg, left eye, neck abscess, etc).

XSpecimens matched with requisition, keeping one copy for lab records.

XSpecimens prepared for transportation to the outside lab in accordance to local operating procedures.

12.5. Specimen Collection. When submitting blood specimens, fasting samples often are the specimen of choice, especially for chemistry procedures. Hemolysis and lipemia interfere with many procedures, therefore, when possible, provide serum or plasma free from hemolysis or lipemia.

12.5.1. SERUM. When drawing blood for a test requiring serum, use:

1. Red Stopper Tube (no anticoagulant or separating gel)
   a. Draw blood into an evacuated tube or syringe without anticoagulant or preservatives. One full 10ml tube is recommended for every 4ml of serum needed.
   b. Allow the blood to clot, then centrifuge within 45 minutes of venipuncture. Centrifuge for approximately 10 minutes. (Caution: prolonged centrifuge may cause hemolysis and evaporation).
2. Mottled Red/Gray Stopper or Cherry Red Stopper Tubes (serum separator tubes containing gel and clot activator).
   a. Follow the same venipuncture technique for serum separator tubes as for red stopper tubes.
   b. Gently invert the tube five to six times to mix the clot activator and blood.
   c. Allow the blood to clot for about 30 minutes. DO NOT REMOVE THE STOPPER. Centrifuge at full speed for 15 minutes. A barrier will form between the serum and the cells. Whether or not red cells are visible above the gel, if a complete barrier is not formed above the cells, either re-spin immediately for five more minutes or transfer the serum to a plastic transfer tube. Do not re-spin if more than an hour has lapsed since venipuncture. The serum below the barrier may be hemolyzed and will contaminate the clear serum above the barrier during re-centrifuging.

12.5.2. PLASMA. When drawing blood for a specimen requiring plasma:

1. Draw blood into a tube containing the appropriate anticoagulant such as EDTA, heparin, or sodium citrate. When using a syringe to draw the specimen, transfer the blood immediately to a tube containing anticoagulant. To prevent hemolysis, puncture the rubber stopper with the syringe needle at an angle so the blood is drawn down the side of the tube. Do not force the blood down the side of the tube. Allow the blood to be drawn into the tube. Overfilling may cause hemolysis, alter the blood/anticoagulant ratio, or cause the stopper to become loose.
2. Promptly invert the tube gently (do not shake) about 10 times to mix the blood and anticoagulant.
3. Centrifuge 5 minutes.
4. Without disturbing the cells, transfer the plasma to a transport tube with a disposable pipette and label the tube PLASMA.

12.5.3. WHOLE BLOOD. When drawing blood for a test requiring Whole Blood:

1. Follow step 1 and 2 as above.
2. When drawing a specimen for a CBC, prepare two blood films from fresh blood and ship them in a slide holder along with the tube of blood.

12.5.4. BLOOD FILM PREPARATION.

1. Put a small drop of fresh, whole blood from a needle or a heel stick onto a frosted slide. Draw a second slide toward the drop of blood at a 45 degree angle.
2. Allow the blood to spread at the junction of the slides. Maintain a 45 degree angle to obtain a smooth, evenly distributed blood film.
3. Push the spreader slide smoothly and quickly down the slide. If the drop of blood is too large, move the slide away from it before starting.
4. A feathered edge usually indicates a good film. Allow the film to air dry. Write the patient's name on the frosted end with a pencil.

12.5.5. URINE COLLECTION.

1. Random urine collections generally are used for qualitative analysis. They should be clean catch, early morning specimens in clean containers with tightly fitting, leak-proof containers.
2. When collecting urine specimens for Culture and Sensitivity testing, give the patient a sterile container. Tell the patient to urinate in the toilet first and then catch a little urine in the container, making sure not to let the genitals touch the sterile container.
3. Twenty-four hour urine collections are required for qualitative analysis. Most tests require collection with a preservative such as Boric Acid or 6N HCL. An aliquot of the 24-hour collection is sufficient for all procedures. Call the contract laboratory and request the proper container for test desired. Be sure to record the 24-hour urine volume on the test request form. (The total volume is required for the calculation of results).

12.5.6. FROZEN SPECIMEN.

1. Allow enough head space in a plastic container to accommodate expansion of the specimen during freezing. Specimen should not be frozen in glass containers.
2. Use a waterproof pen or marker to label the specimen with the patient's name, A#, and date the specimen was collected. Include total volume if the specimen is a timed urine collection.
3. Freeze the specimen immediately.
4. If more than one test is ordered on a specimen that requires freezing, send a separate specimen for each test ordered. Thawing a specimen to split it for different procedures damages specimen integrity.
5. Complete the request slip with patient's name, A#, date, and test required.
6. SHIP SPECIMEN FROZEN with a dry ice coolant. Specimen must remain frozen during transit.

12.5.7. INFECTIOUS (ETIOLOGIC) AGENTS.

1. Blood Cultures: Use two bottles per venipuncture for isolation of both aerobes and anaerobes.
2. Bacterial or Fungal Culture: Red cap swab with tube of stabilizing medium for viral specimen transport.
3. Virus Isolation: Blue cap swab with tube of stabilizing medium for viral specimen transport.
4. Chlamydia Isolation: Sterile Dacron or rayon swab (not cotton or calcium alginate) and Chlamydia stabilizing medium.
5. N. Gonorrhea Culture: Jembec medium.
6. Gonococcal (GC) Antigen (Urogenital), EIA Chlamydia Antigen, EIA: Brown cap tubes with swabs for male and female. Tubes contain 0.1 ml storage fluid for specimen transport. These swabs are not suitable for culture.
7. Ova and Parasite Detection (O&P): Two containers, one with 10% formalin and one with PVA.
8. Urine or Fluid Culture: Sterile plastic 15ml tube or 100ml cup, each with a tight fitting cap.
9. Urine Culture: Red cap tube with maintenance pill. Do not refrigerate.

12.6. HIV Testing. All HIV testing will be handled with strict confidentiality and proper counseling to the patient. All HIV testing must be ordered by the physician or designee. The request must be documented in the patient's record. The patient must be advised as to the nature of the test and must sign a consent form prior to having blood drawn utilizing the Pre and Post HIV Test Counseling and Consent (DIHS 075). All specimens should be submitted with coded name designations to ensure patient anonymity.

Example: no name / date / sex / age / Alien number

When the results are obtained, the patient should be counseled as to the significance of the results. For more information, see section 8.11.

12.7. CLIA waived tests. CLIA requires all laboratories that examine materials derived from the human body for the diagnosis, prevention, or treatment purposes to be certified by the Secretary of Health and Human Services. The Health Care Financing Administration (HCFA) operates CLIA laboratory certification program for the Secretary in conjunction with the Centers for Disease Control and the Food and Drug Administration. By the CLIA law, waived laboratories perform only tests that are determined by FDA or CDC to be so simple that there is little risk of error. DIHS medical facilities may perform certain CLIA waived tests on site (See section 12.1).

12.7.1. Procedure. Each CLIA waived test will be performed in accordance with the manufacturers instructions. Local Operating Procedures will reflect these procedures.

12.7.2. Quality Control. Each CLIA waived test must have quality control testing performed on a regular basis in accordance with manufacturers instructions. Local Operating Procedures will reflect these monitoring processes.